UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 21, 2011

MEMORANDUM

SUBJECT: Efficacy Review for EPA Reg. No. 9480-4, Sani-Cloth Germicidal Wipes;
DP Barcode: D396047

FROM: Leah Harman, Biologist
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Regulatory Management Branch I
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APPLICANT: Professional Disposables International, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962

Formulations from Label:

Active Ingredient(s)	% by wt.
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chloride.....	0.25%
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride.....	0.25%
Other Ingredients.....	99.50%
Total	100.00%

I BACKGROUND

The product, Sani-Cloth Germicidal Wipes (EPA Reg. No. 9480-4), is an EPA-approved disinfectant (bactericide, tuberculocide, virucide) and deodorizer for use on hard, non-porous surfaces in commercial, institutional, industrial, and hospital or medical environments. In response to questions raised under the Agency's Antimicrobial Testing Program (ATP), the applicant conducted additional testing of its product to confirm effectiveness as a disinfectant against *Pseudomonas aeruginosa* and *Staphylococcus aureus*. The label states that the product is effective in the presence of 5% blood serum. Studies were conducted at MycoScience Labs, Inc., located at 25 Village Hill Road in Willington, CT 06279.

This data package contained a letter from the applicant's representative to EPA (dated October 17, 2011), two studies (MRID 486310-01 and 486310-02), and Statements of No Data Confidentiality Claims for both studies.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: ambulance equipment, bathroom fixtures, bathtubs, bed railings, cabinets, carts, cash registers, chairs, changing tables, computers, counters, cribs, desks, diagnostic equipment, dialysis machines, diaper changing stations, diaper pails, doorknobs, endodontic equipment, examination tables, faucets, filing cabinets, floors, garbage cans, grocery cart child seats and handles, gym equipment, hampers, hand rails, handles, headsets, hospital equipment (e.g., gurneys, IV poles, operatory light switches, oxygen hoods, spine backboards, stethoscopes, stretchers, ultrasound transducers and probes), infant incubators, instrument trays, laboratory equipment, keyboards, patient monitoring equipment, patient support and delivery equipment, physical therapy equipment, railings, respiratory therapy equipment, seats, shower stalls, showers, sinks, tables, telephones, toilet seats, toilets, toys, trash cans, urinals, vanity tops, and work stations. The product label indicates that the product may be used on hard, non-porous surfaces, including: Formica, glass, glazed tile, plastic, and stainless steel. Directions on the product label provide the following information regarding use of the product as a disinfectant: Use a wipe to remove heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for 2 minutes. Use additional wipe(s), if needed, to assure continuous 2-minute wet contact time. Let air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

<u>Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes</u>

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the

surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 486310-01 "Professional Disposables International, Inc. Efficacy Study of Single Use Impregnated Towelettes for Hard Surface Disinfection," Test Organism: *Pseudomonas aeruginosa* (ATCC 15442), for Sani-Cloth Germicidal Wipes Germicidal Disposable Cloth (EPA Reg. No. 9480-4), by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – September 23, 2011. Project Number 11-1166 NPNY.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot No. 11101330) of the product, Sani-Cloth Germicidal Wipes Germicidal Disposable Cloth (EPA Reg. No. 9480-4), was tested using the AOAC Germicidal Spray Products as Disinfectants Method (modified for towelette products) as described in the AOAC Official Methods of Analysis, 17th Edition, 2005. The product lot tested appears to have been at least 60 days old at the time of testing (based on study initiation date and manufacturing date, the lots are >60 days old). The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Twelve (12) glass carriers (6 inch x 6 inch) were inoculated with 0.1 mL of a 24 hour old suspension of test organism, so that the total inoculum volume was 0.4 mL per one 1 foot x 1 foot glass surface. Inoculum was uniformly spread over the surface of each carrier. The carriers were dried for 30 minutes at room temperature. Each glass carrier was wiped with a saturated towelette with one wipe back and forth for a total of two passes. One towelette was used to treat 4 carriers. The carriers were allowed to remain wet for 2 minutes at 24-25°C at 42-44% relative humidity. Following the exposure period, the four

carriers treated by a single wipe were transferred to a single sterile composite bag containing 800 mL of AOAC Neutralizing Broth to neutralize. After wiping the final surface section and after 2 minutes time, approximately 0.1 mL of liquid was expressed from the wipe into a sterile jar containing 100 mL of AOAC Neutralizing Broth. The bag containing the carriers was sealed and sonicated for 5 minutes in an ultrasonic bath. A membrane filtration technique was used to determine surviving numbers of the challenge microorganism. The entire volume of the glass surface extract and the corresponding volume of the wipe-expressed aliquot in AOAC Neutralizing Broth were filtered through individual sterile bacterial retentive filters followed by a 50 mL rinse with AOAC Neutralizing Broth. The filters were transferred to Tryptone Glucose Extract Agar plates containing neutralizers and were incubated for 48 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for suspension count, positive control count, purity, sterility, and neutralization confirmation (the single product lot).

2. MRID 486310-02 "Professional Disposables International, Inc. Efficacy Study of Single Use Impregnated Towelettes for Hard Surface Disinfection," Test Organism: *Staphylococcus aureus* (ATCC 6538), for Sani-Cloth Germicidal Wipes Germicidal Disposable Cloth (EPA Reg. No. 9480-4), by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – September 26, 2011. Project Number 11-1165 NPNY.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 11101330) of the product, Sani-Cloth Germicidal Wipes Germicidal Disposable Cloth (EPA Reg. No. 9480-4), was tested using the AOAC Germicidal Spray Products as Disinfectants Method (modified for towelette products) as described in the AOAC Official Methods of Analysis, 17th Edition, 2005. The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Twelve (12) glass carriers (6 inch x 6 inch) were inoculated with 0.1 mL of a 24 hour old suspension of test organism, so that the total inoculum volume was 0.4 mL per one 1 foot x 1 foot glass surface. Inoculum was uniformly spread over the surface of each carrier. The carriers were dried for 30 minutes at room temperature. Each carrier was wiped with a saturated towelette with one wipe back and forth for a total of two passes. One towelette was used to treat 4 carriers. The carriers were allowed to remain wet for 2 minutes at 24-25°C at 37-42% relative humidity. Following the exposure period, the four carriers treated by a single wipe were transferred to a single sterile composite bag containing 800 mL of AOAC Neutralizing Broth to neutralize. After wiping the final surface section and after 2 minutes time, approximately 0.1 mL of liquid was expressed from the wipe into a sterile jar containing 100 mL of AOAC Neutralizing Broth. The bag containing the carriers was sealed and sonicated for 5 minutes in an ultrasonic bath. A membrane filtration technique was used to determine surviving numbers of the challenge microorganism. The entire volume of the glass surface extract and the corresponding volume of wipe-expressed aliquot in AOAC Neutralizing Broth were filtered through individual sterile bacterial retentive filters followed by a 50 mL rinse with AOAC Neutralizing Broth. The filters were transferred to Tryptone Glucose Extract Agar plates containing neutralizers and were incubated for 48 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for suspension count, positive control count, purity, sterility, and neutralization confirmation (the single product lot).

Note: The laboratory reported a failed study set up on July 28, 2011. In the study, the positive control did not meet the acceptance criterion. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on August 4, 2011. See pages 9 and 16 of the laboratory report.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Positive Control Count (CFU/ft^2)
		Replicate 1	Replicate 2	Replicate 3	
2-Minute Exposure Time					
486310-01	*Pseudomonas aeruginosa*	0 / 1	0 / 1	0 / 1	4.2×10^5
486310-02	*Staphylococcus aureus*	0 / 1	0 / 1	0 / 1	2.5×10^5

VI CONCLUSIONS

1. The submitted efficacy data support the use of the towelette product, Sani-Cloth Germicidal Wipes Germicidal Disposable Cloth (EPA Reg. No. 9480-4), as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 2-minute contact time:

Pseudomonas aeruginosa MRID 486310-01
Staphylococcus aureus MRID 486310-02

Complete killing was observed in the subcultures of the carriers tested against one product lot, using a testing method for large carriers. Neutralization confirmation testing confirmed neutralizer effectiveness. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The product label claims that the towelette product, Sani-Cloth Germicidal Wipes, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% serum for a 2-minute contact time:

Pseudomonas aeruginosa
Staphylococcus aureus

These claims are acceptable as they are supported by the submitted data.